

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1. (Currently Amended) A ~~stable~~-lipid assembly, being an organized collection of lipids, comprising:

(a) a biologically active lipid having a hydrophobic region and a polar headgroup, wherein the atomic mass ratio between the headgroup and hydrophobic region is less than 0.3;

(b) a lipopolymer having a hydrophobic lipid region and a hydrophilic polymer headgroup, wherein the atomic mass ratio between the headgroup and hydrophobic region is at least 1.5; the lipid assembly being chemically and physically stable under storage conditions of 4°C in biological fluids, for at least six months.

2. (Original) The lipid assembly of Claim 1, comprising a lipid matrix, the lipid matrix comprising a lipid

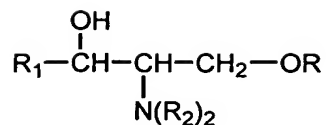
or a combination of lipids having an additive packing parameter in the range of 0.74-1.0.

3. (Currently Amended) The lipid assembly of ~~Claim 1 or 2~~ Claim 1, having a level of water tightly bound to said lipopolymer headgroup of at least about 60 molecules of water per lipopolymer headgroup.

4. (Currently Amended) The lipid assembly of ~~any of Claims 1-3~~ Claim 2, wherein said biologically active lipid has a packing parameter which is greater than 1.

5. (Currently Amended) The lipid assembly of ~~any of Claims 1-4~~ Claim 2, wherein said biologically active lipid is selected from ceramides, ceramines, sphinganine, sphinganine-1-phosphate, di- or tri-alkylsphingosines and their structural analogs.

6. (Currently Amended) The lipid assembly of ~~Claim 1 or 5~~ Claim 5, wherein said biologically active lipid has the following general formula (I):



wherein

- R₁ represent a C₂-C₂₆, saturated or unsaturated, branched or unbranched, aliphatic chain, the aliphatic chain may be substituted with one or more hydroxyl or cycloalkyl groups and may consist of a cycloalkylene moiety;
- R₂ which may be the same or different, represents a hydrogen, a C₁-C₂₆ saturated or unsaturated, branched or unbranched chain selected from aliphatic, aliphatic carbonyl; a cycloalkylene-containing aliphatic chain, the aliphatic chain may be substituted with an aryl, arylalkyl or arylalkenyl group;
- R₃ represents a hydrogen, a methyl, ethyl, ethenyl or a phosphate group.

7. (Original) The lipid assembly of Claim 6, wherein said biologically active lipid is a C₂-C₂₆ ceramide.

8. (Original) The lipid assembly of Claim 6,

wherein said biologically active lipid is
N,N-dimethylsphingosine (DMS).

Claim 9 (Cancelled)

10. (Currently Amended) The lipid assembly of ~~Claims 1 or 9~~ Claim 1, wherein said lipopolymer comprises a polymer headgroup selected from polyethylene glycol (PEG), polysialic acid, polylactic acid, polyglycolic acid, apolylactic-polyglycolic acid, polyvinyl alcohol, polyvinylpyrrolidone, polymethoxazoline, polyethyloxazoline, polyhydroxyethyloxazoline, polyhydroxypropyloxazoline, polyaspartamide, polyhydroxypropyl methacrylamide, polymethacrylamide, polydimethylacrylamide, polyvinylmethylether, polyhydroxyethyl acrylate, derivatized celluloses.

11. (Currently Amended) The lipid assembly of Claim ~~10~~9, wherein said polymer headgroup is polyethylene glycol (PEG) having an atomic mass in the range of about 750Da to about 20,000 Da.

Claim 12 (Cancelled)

13. (Currently Amended) The lipid assembly of Claim ~~12~~10, wherein said PEG has an atomic mass of 2,000Da (2kPEG).

14. (Original) The lipid assembly of Claim 2, wherein said lipid matrix comprises a phospholipid.

Claim 15 (Cancelled)

16. (Currently Amended) The lipid assembly of Claim ~~15~~12, wherein said phospholipid is a glycerophospholipid selected from phosphatidylglycerol (PG), phosphatidylcholine (PC), phosphatidic acid (PA), phosphatidylinositol (PI), phosphatidylserine (PS) and sphingomyelin (SPM) and derivatives of the same.

17. (Currently Amended) The lipid assembly of ~~any of Claims 2, 14-16~~ Claim 2, wherein said lipid matrix comprises a cationic lipid.

18. (Original) The lipid assembly of Claim 17, wherein said cationic lipid is a monocationic lipid having a

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headgroup selected from 1,2-dimyristoyl-3-trimethylammonium propane (DMTAP) 1,2-dioleyloxy-3-(trimethylamino) propane (DOTAP); N-[1-(2,3,- ditetradecyloxy)propyl]-N,N-dimethyl-N-hydroxyethylammonium bromide (DMRIE); N-[1-(2,3,- dioleyloxy)propyl]-N,N-dimethyl-N-hydroxy ethyl- ammonium bromide (DORIE); N-[1-(2,3-dioleyloxy) propyl]-N,N,N-trimethylammonium chloride (DOTMA); 3β [N-(N',N'-dimethylaminoethane) carbamoyl] cholesterol (DC-Chol); and dimethyl-dioctadecylammonium (DDAB).

19. (Original) The lipid assembly of Claim 18, wherein said cationic lipid is a polycationic lipid having a headgroup selected from spermine or spermidine.

20. (Original) The lipid assembly of Claim 19, wherein said polycationic lipid is N-[2-[[2,5-bis[3-aminopropyl)amino]-1-oxopentyl]amino]ethyl]-N,N-dimethyl-2,3-bis[(1-oxo-9-octadecenyl)oxy]-1-propanaminium (DOSPA) or ceramide carbamoyl spermine (CCS).

Claims 21-25 (Cancelled).

26. (Currently Amended) A pharmaceutical composition comprising a physiologically acceptable carrier and an amount of a stable lipid assembly, the amount being sufficient to achieve a biological effect at a target site, the lipid assembly comprising:

(a) a biologically active lipid having a hydrophobic region and a polar headgroup, wherein the atomic mass ratio between the headgroup and hydrophobic region is less than 0.3;

(b) a lipopolymer having a hydrophobic lipid region and a hydrophilic polymer headgroup, wherein the atomic mass ratio between the headgroup and hydrophobic region is at least 1.5; the lipid assembly being chemically and physically stable under storage conditions of 4oC in biological fluids, for at least six months.

Claims 27-53 (Cancelled).

54. (Original) A method for the treatment or prevention of a disease, disorder or pathological condition comprising providing an individual in need of said treatment, in a manner so as to achieve a therapeutic effect, an effective

amount of a stable lipid assembly comprising:

(a) a biologically active lipid having a hydrophobic region and a polar headgroup, wherein the atomic mass ratio between the headgroup and hydrophobic region is less than 0.3;

(b) a lipopolymer having a hydrophobic lipid region and a polymer headgroup, wherein the atomic mass ratio between the headgroup and hydrophobic region is at least 1.5.

Claims 55-80 (Cancelled).